

CLAIMS

1.

A composition comprising:

a plurality of discrete, substantially flat flakes, each having an average length, an average width and an average thickness, wherein each of the length and width are at least three times the thickness, wherein a longest dimension of each flake is between 100 nanometers and 5 millimeters, and wherein the flakes comprise a drug of a nondrug active agent.

2. The composition of claim 1, wherein each of the flakes has a surface area, and wherein the ratio of the surface area to the thickness is at least 25 units:1 unit.

3. The composition of claim 2, wherein the longest dimension of each flake is between 10 microns and 1 millimeter and wherein the ratio is at least 100 units:1 unit.

4. The composition of any one of claims 1-3, wherein the drug comprises at least 5% by weight of the flakes.

5. The composition of any one of claims 1-3, wherein the drug comprises at least 10% by weight of the flakes.

6. The composition of any one of claims 1-3, wherein the drug comprises at least 25% by weight of the flakes.

7. The composition of any one of claims 1-3, wherein the drug comprises at least 50% by weight of the flakes.

8. The composition of anyone of claims 1-3, wherein the drug is embedded in the flakes.

9. The composition of any one of claims 1-3, wherein the drug is coated on the flakes.

10. The composition of any one of claims 1-3, wherein the drug is contained in microspheres embedded within or coated on the flakes.

11. The composition of any one of claims 1-3 further comprising a coating on the flakes which separates the drug from the environment.

12. The composition of any one of claims 1-3 further comprising an enteric coating covering the flake.

13. The composition of any one of claims 1-3, wherein the flake comprises at least two layers, each of said layers being of a different composition.

14. The composition of claims 1-3, wherein at least two layers is at least three layers.

15. The composition any one of claims 1-3, wherein the flake comprises at least 25% by weight of a natural polymer.

16. The composition of any one of claims 1-3, wherein the flake comprises a synthetic polymer.

17. The composition of any one of claims 1-3, wherein the flake comprises a drug uptake enhancer.

18. The composition of any one of claims 1-3, wherein the flake is at least 5% by weight a nonfood.

19. The composition of any one of claim 1-3, wherein the flake is at least 10% by weight a nonfood.

20. A composition comprising:  
a plurality of discrete, substantially flat flakes, each having an average length, an average width and an average thickness, wherein each of the length and width are at least three times the thickness, wherein a longest dimension of each flake is between 100 nanometers and 5 millimeters, and wherein each flake comprises a porous matrix.

FOOTNOTES

DRUG

NO

CONSLAKO?

21. The composition of claim 20 further comprising a drug contained in the porous matrix.

22. The composition of claim 20, wherein the flakes are at least 5% by weight nonfood.

23. A pharmaceutical preparation comprising the composition of any one of claims 1-19, and a pharmaceutically acceptable carrier, wherein the drug is present in an amount effective for treating a condition.

24. The pharmaceutical preparation of claim 13 formulated as a dosage form, selected from the group consisting of: an oral dosage form, a topical dosage form and an implantable dosage form.

25. The pharmaceutical preparation of claim 23, wherein the preparation contains an agent nonsuitable for oral ingestion.

26. The pharmaceutical preparation of claim 23, wherein the pharmaceutically acceptable carrier is a semi-solid.

27. The pharmaceutical preparation of claim 23, wherein the pharmaceutically acceptable carrier is a hydrogel.

28. The pharmaceutical preparation of claim 23, wherein the pharmaceutically acceptable carrier is a semi-solid food.

29. A method of treating a subject having a condition, with a drug, comprising: administering to a subject in need of such treatment an amount of the drug effective to treat the condition, wherein the drug comprises a plurality of flakes.

30. The method of claim 29, wherein the flakes comprise the pharmaceutical preparation of claim 23.

31. The method of claim 29, wherein the flakes comprise the pharmaceutical preparation of claim 24.

32. The method of claim 29, wherein the flakes comprise the pharmaceutical preparation  
5 of claim 25.

33. The method of claim 29, wherein the flakes comprise the pharmaceutical preparation of claim 26.

10 34. The method of claim 29, wherein the flakes comprise the pharmaceutical preparation of claim 27.

35. The method of claim 29, wherein the flakes comprise the pharmaceutical preparation of claim 28.

15 36. The method of claim 29, wherein the flakes are administered orally.

37. The method of claim 29, wherein the subject is selected from the group consisting of a geriatric subject, a subject with cancer, a subject who is post-surgically recovering, a child 5 years or younger and a pregnant mother.

20 38. In a method for preparing a pharmaceutical preparation by incorporating a drug within or coating a drug onto a particle, the improvement comprising incorporating the drug within or onto a flake.

25 39. The improvement of claim 35, wherein the flake comprises:  
a plurality of discrete, substantially flat flakes, each having an average length, an average width and an average thickness, wherein each of the length and width are at least three times the thickness, wherein a longest dimension of each flake is between 100 nanometers and 5  
30 millimeters.

40. A method for preparing a pharmaceutical preparation comprising incorporating a drug into or upon a plurality of flakes.

5

a plurality of discrete, substantially flat flakes, each having an average length, an average width and an average thickness, wherein each of the length and width are at least three times the thickness, wherein a longest dimension of each flake is between 100 nanometers and 5 millimeters.

10